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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,325	09/12/2005	Kevin Woehr	54104/THD/K163	5105
23363 7590 09/26/2008 CHRISTIE, PARKER & HALE, LLP PO BOX 7068 PASADENA, CA 91109-7068				
EXAMINER ANDERSON, MICHAEL J				
ART UNIT		PAPER NUMBER		
3767				
MAIL DATE		DELIVERY MODE		
09/26/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/520,325

**Applicant(s)**

WOEHR, KEVIN

**Examiner**

MICHAEL J. ANDERSON

**Art Unit**

3767

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 9-13, 16 and 17 is/are rejected.
- 7) ☒ Claim(s) 3, 5-8, 14-15 and 18-20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

In view of the appeal brief filed on 7/2/2008, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 9-13, and 16-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Villa (WO 03/011381 A1).

With regards to claim 1, Villa discloses (figures 1-13) a catheter insertion device (4) comprising a hollow-cylindrical catheter hub (11) having a catheter tube (10) attached at a distal end thereof, a needle hub (6) having a hollow needle (5) attached thereto and extending through the catheter hub and the catheter tube when in a ready position, a needle guard element (19) arranged displaceably on the needle in the catheter hub and having an engaging section which engages with an engaging means (31) formed near the needle tip when the hollow needle is removed from the catheter hub, wherein a check valve (16) is disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in the ready position and which automatically closes after the removal of the needle.

With regards to claim 2, Villa discloses (figures 1-13) the device according to claim 1, wherein the catheter hub comprises a distal hub element and a proximal hub element, and the check valve (16) is held between the distal hub element and the proximal hub element, which are joined to one another.

With regards to claim 4, Villa discloses (figures 1-13) the device according to claim 1, wherein the catheter hub comprises an inner circumference and a radial projection projecting radially from the inner circumference, which is configured to engage with the needle guard element in the ready position (35-37, figure 9).

With regards to claim 9, Villa discloses (figures 1-13) the device according to claim 1, wherein the needle guard element is formed as a spring clip which has

diametrically opposite spring arms starting from a rear wall provided with a bore, wherein bent end sections of the spring arms overlap and block the needle tip when the engaging means of the needle comes to abut on the rear wall (figures 9 and 10).

With regards to claim 10, Villa discloses (figures 1-13) a catheter insertion device comprising: a catheter tube attached to an end of a catheter hub, the catheter tube comprising a lumen and the catheter hub comprising an interior cavity; a needle defining a needle axis attached to an end of a needle hub, said needle projecting, through the lumen of the catheter tube; a valve for regulating fluid flow positioned inside the interior cavity of the catheter hub; and a needle guard element comprising two needle guard arms (figures 1 and 8) crossing the needle axis of the needle positioned inside the catheter hub adjacent the valve.

With regards to claim 11, Villa discloses (figures 1-13) a catheter insertion device comprising: a catheter tube attached to an end of a catheter hub, the catheter tube comprising a lumen and the catheter hub comprising an interior cavity; a needle defining a needle axis attached to an end of a needle hub, said needle projecting, through the lumen of the catheter tube and comprising an engaging section (31) near a needle tip; a valve (16) for regulating fluid flow positioned inside the interior cavity of the catheter hub, said valve comprising an opening and the needle projecting through the opening; and a needle guard element comprising an opening adapted to contact the engaging section of the needle positioned between the valve and the needle hub (figures 1 and 8).

With regards to claim 12, Villa discloses (figures 1-13) the catheter insertion device of claim 10, wherein the two needle guard arms cross one another (figure 8).

With regards to claim 1, Villa discloses (figures 1-13) the catheter insertion device of claim 10, wherein the needle guard element comprises a proximal wall comprising an opening having the needle passing therethrough.

With regards to claim 16, Villa discloses (figures 1-13) the catheter insertion device of claim 11, wherein the engaging section (31) is crimp.

With regards to claim 17, Villa discloses (figures 1-13) catheter insertion device of claim 11, wherein the needle guard further comprises at least one arm comprising an apex abutting a shoulder located on the interior surface of the catheter hub (figures 1 and 8).

#### ***Allowable Subject Matter***

Claims 3, 5-8, 14-15 and 18-20 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Response to Amendment***

The present communication responds to the Amendment of 7/2/2008. By this communication, no claims were amended. The amendments did not add new matter. Claims 1-20 are pending. The rejection(s) are as stated.

***Response to Arguments***

Applicant's arguments, see pages 4-11, filed 7/2/2008, with respect to the rejection(s) of claim(s) 1-20 under 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Villa.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J. ANDERSON whose telephone number is (571)272-2764. The examiner can normally be reached on M-F 6:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael J Anderson/  
Examiner  
Art Unit 3767

MJA  
9/23/2008  
/Kevin C. Sirmons/  
Supervisory Patent Examiner, Art Unit 3767